3554836-X-00-01

VOLUNTARY reporting professionals of adverse and product problems

Form Approved: OMB No. 0910-0291 Expires:12/31/94
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 12765

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted] 4889 In confidence		☐ female ☑ male	____ lbs or ____ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☑ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr): 5/3/00

4. Date of this report (mo/day/yr): 8/16/00

5. Describe event or problem

ade_id	adr_desc
4889	54 YOM adm to [redacted] on 5/3 with 2 day hx of fever to 102, inc SOB, nonproductive cough for R/O pneumonia. Pt adm here on 5/4 when it was determined that pt had fulminant hepatic failure from APAP ingestion for transIpnat eval. Over a 3 day period, pt had ingested approximately #32 - 325 mg tablets (10.4GM) for his fevers. APAP level >24H out at 12.3. ALT 7889, AST 9215, ALK phos 95, INR 2.5, Tbili 2. Hep B/C negative. Pt prev bartender, but on PE no evidence of any preexistent cirrhosis.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

-NKDA

-HTN, CAD

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Acetaminophen
#2

2. Dose, frequency & route used
#1 #32 x 325mg PO
#2 prn

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 5/1/00 - 5/3/00
#2

4. Diagnosis for use (indication)
#1 Persist fevers
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☑ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☑ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
Cyclophosphamide, Prednisone, Hyzaar.

D. Suspect medical device

1. Brand name

2. Type of device DSS

3. Manufacturer name & address

AUG 23 2000
RECEIVED
AUG 22 2000
MEDWATCH CTU

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ____

5. Expiration date (mo/day/yr)

6.
model # ____
catalog # ____
serial # ____
lot # ____
other # ____

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted], PharmD

2. Health professional? ☑ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FV12765

FDA Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.